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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/444,790	05/19/1995	MANFRED BROCKHAUS	9189	5612

151 7590 08/21/2002  
HOFFMANN-LA ROCHE INC.  
PATENT LAW DEPARTMENT  
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EXAMINER

MURPHY, JOSEPH F

ART UNIT PAPER NUMBER

1646

DATE MAILED: 08/21/2002

37

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

08/444,790

Applicant(s)

BROCKHAUS ET AL.

Examiner

Joseph F Murphy

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 October 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 55 and 62-77 is/are pending in the application.
- 4a) Of the above claim(s) 55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 62-77 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 34,35.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1646

## **DETAILED ACTION**

### ***Formal Matters***

Claims 55, 62-77 are pending. Claim 55 stands withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 62-77 are under consideration.

### ***Response to Arguments***

Applicant's arguments filed 10/26/2001 have been fully considered but they are not persuasive for the reasons set forth below.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 62-77 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,981,701 (Wallach et al.), for reasons of record set forth in Paper No. 32, 4/17/2002, and as evidenced by U.S. Patent No. 5,811,261 (Wallach et al.).

The rejection of record set forth that Wallach discloses purification of a tumor necrosis factor inhibitory protein, which interacts with TNF and inhibits the binding of TNF to its receptors and the cytotoxic effects of TNF (column 3 line 65 to column 4 line 4). The protein disclosed in Wallach has a molecular weight of 40-80 kD (column 16 line 44), and comprises an amino acid sequence that is identical to the sequence of the protein claimed in the instant application (column 16, line 56), thus claims 62-66, 69, 72, 75 are anticipated. Wallach further

Art Unit: 1646

sets forth the methods to produce the TNF inhibitor protein recombinantly from host cells (column 12, line 11-column 15, line 53), thus anticipating claims 67-68, 70-71, 73-74, 76-77.

Applicant argues that the TNF inhibitory protein disclosed by Wallach is a different protein that can be isolated from human urine (Paper No. 34 at 2) and that the amino acid sequence of the Wallach protein is different from the protein claimed in the instant application in that they have different amino terminal sequences (Paper No. 34 at 3). However, the full amino acid sequence of the TNF inhibitory protein of Wallach is set forth in the '261 patent (see SEQ ID NO: 2). The sequence of SEQ ID NO: 2 of the '261 patent is 100% identical to the amino acid sequence of the protein claimed in the instant application, and is 100% identical from amino acids 1-180 of the protein claimed in the instant application. Thus, claims 62-66, 69, 72, 75 are anticipated. The methods to produce the TNF inhibitor protein recombinantly from host cells are disclosed in the Wallach patent (column 12, line 11-column 15, line 53), thus anticipating claims 67-68, 70-71, 73-74, 76-77.

Claims 62-77 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,811,261 (Wallach et al.).

The '261 patent discloses purification of a tumor necrosis factor inhibitory protein, which interacts with TNF and inhibits the binding of TNF to its receptors and the cytotoxic effects of TNF (column 2 lines 1-3). The protein disclosed in the '261 patent has a molecular weight of 40-80 kD (column 9 lines 34-35). the full amino acid sequence of the TNF inhibitory protein of Wallach is set forth in the '261 patent (see SEQ ID NO: 2). The sequence of SEQ ID NO: 2 of the '261 patent is 100% identical to the amino acid sequence of the protein claimed in the instant

Art Unit: 1646

application, and is 100% identical from amino acids 1-180 of the protein claimed in the instant application. Thus, claims 62-66, 69, 72, 75 are anticipated. The methods to produce the TNF inhibitor protein recombinantly from host cells are disclosed in the Wallach patent (column 12, line 11-column 15, line 53), thus anticipating claims 67-68, 70-71, 73-74, 76-77.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
August 15, 2002